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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/567,411

02/06/2006

Markus Zabel

3286-102

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08/06/2008

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

1425 K STREET, N.W.

SUITE 800

WASHINGTON, DC 20005

EXAMINER

PATEL, NATASHA

ART UNIT

PAPER NUMBER

3766

NOTIFICATION DATE

DELIVERY MODE

08/06/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/567,411 | Applicant(s) ZABEL ET AL. | |
| | Examiner NATASHA N. PATEL | Art Unit 3766 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/6/06; 8/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower (US Patent 5,711,304) in view of Evans et al. (US Patent 5,377,687).

3. Regarding Claims 1, 2, 4, 11, 17, and 18, Dower discloses an ECG system for large-surface recording of ECG signals, characterized by a first measuring means (10) for generating a first measured data record including at least one reading of the cardiac currents (V1-V6) at least one lead site of the first measuring means (10) being variable during the recording of the large-surface ECG signals (see col. 6, lines 45-62), a second measuring means (20) for simultaneously generating a second measured data record including at least one reading of the cardiac currents (see RA, RL, LL, and LA), the lead site of the second measuring means (20) being spatially invariable during the recording of the large-surface ECG signals in order to obtain continuous measurement results (see col. 1, lines 32-41), and a data processing system (30) having a means for synchronizing at least two signals (see col. 13, lines 33-40) of the first measured data record with at least one continuously detected signal of the second measured data record. The examiner considers that the lead sites in the first measuring means are

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variable they can be switched from synthesized to unsynthesized (see col. 6, lines 45-62 and col. 7, lines 28-40). Furthermore, the examiner considers the exploring electrode to be a part of the first measuring means (see col. 2, lines 8-25). The examiner considers that the second measuring means would be spatially invariable during recording because one would not want to move a grounding electrode during recording since that would defeat the purpose of noise elimination. Dower does not disclose that the two signals are determined in a temporally offset fashion. Evans discloses a similar mapping analysis wherein the signals are determined in a temporally offset fashion (see col. 11, lines 24-33). It would have been obvious to one of ordinary skill in the art at the time of the invention to try and collect signals even if they are in an offset manner because doing so provides a larger amount of data to work with later. As shown by Evans, the data can always be manipulated and cleaned up later on (see col. 11, lines 24-33). Evans further discloses a means for correcting the baseline of individual cardiac currents (see col. 11, lines 24-33).

4. Regarding Claim 3, Modified Dower discloses cardiac currents from a temporal sequence of thorax leads (V1 - V6) at different thorax positions (see Figure 1).

5. Regarding Claim 5, Modified Dower discloses that the second measured data record includes at least one measurement of the cardiac currents of all the extremity leads (see Figure 4).

6. Regarding Claim 6, Dower discloses that the synchronization is performed with the aid of at least one prominent signal pattern of the second measured data record (see col. 6, line 63-col. 7, line 17).

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7. Regarding Claims 7-9, Dower does not elaborate on the specific portions of the ECG waves. Evans discloses signal patterns as well wherein the R wave in the second measured data record is used for the purpose of combining the signals (see col. 5, lines 16-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to use distinguishing characteristics of the ECG signal waveform because Evans teaches that doing so reduces the complexity of map analysis (see col. 5, lines 16-26).

8. Regarding Claim 10, Dower does not elaborate on the specific steps of processing the signals. Evans discloses a filter, a means for averaging and/or for determining the median for signals of the first measured data record and/or of the second measured data record (see col. 24, lines 56-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to use averaging or any other means of filtering the data because Evans teaches that doing so allows for easier and more accurate analysis (see col. 24, lines 65-col. 25, line 2).

9. Regarding Claim 12, Dower discloses a visual display (see col. 8, lines 29-34). Dower does not explicitly disclose the amplitudes though. Evans discloses a similar processing system (see CPU 32) that uses the amplitude values of all the thorax readings to determine a graphic display of the instantaneous potential distribution automatically for any desired instant of a measurement relative to a time reference obtained by means of a signal of the second measured data record (see col. 11, lines 34-50).

10. Regarding Claim 13, Evans discloses that the graphic display is a QRST integral map display (see col. 11, lines 60-65 and col. 12, lines 17-24).

11. Regarding Claims 15 and 16, Evans discloses variance of the measurement results can be ascertained with the aid of a measure of specific ECG potential levels, in particular R-R intervals, QT times and/or of a comparison of a mean value of a measure of an ECG potential level of one measurement phase with the mean value for measures of ECG potential levels of all the measurement phases (see col. 20, lines 34-56).

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dower (US Patent 5,711,304) and Evans et al. (US Patent 5,377,687) in view of Mills (US Patent 4,608,987).

13. Regarding Claim 14, neither Dower nor Evans disclose the specifics of attaching the electrodes to the patient's chest. However, Mills teaches that such devices include various forms, including vests (see Abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a vest to hold the electrodes because Mills teaches that a vest provides better electrical engagement with the patient's skin (see abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATASHA N. PATEL whose telephone number is (571)272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Natasha N Patel/
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766